

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: DIGITEK
PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO:

ALL CASES

**PLAINTIFFS' MOTION TO COMPEL
DOCUMENTS AND DEPOSITION TESTIMONY**

The Plaintiffs' Steering Committee ("PSC") respectfully requests that this Court enter an order compelling Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC ("Defendants Actavis") to produce documents and provide testimony relating to their Good Manufacturing Practices compliance audits.

**I
INTRODUCTION**

On December 9, 2009, Plaintiffs took the deposition of Actavis Totowa LLC's Director of Quality Assurance Operations, Paul Galea, who testified that he performed an audit of Actavis Totowa LLC in 2007, approximately one year before the Digitek recall. The purpose of this audit was to determine whether Actavis Totowa LLC's manufacturing, packaging and testing operations were in compliance with Good Manufacturing Practices ("GMPs") as set forth in Title 21 of the Code of Federal Regulations. Asserting the "self-critical analysis" privilege, counsel

for Defendants Actavis repeatedly instructed Mr. Galea not to answer questions relating to his audit and Mr. Galea complied.

Plaintiffs contend that the self-critical analysis privilege should not be recognized in the present litigation for the following reasons:

- (A) Defendants Actavis failed to assert the self-critical analysis privilege in response to Plaintiffs' requests for documents relating to audits and in their Privilege Log, thereby waiving the privilege.
- (B) Federal and state courts, including those in West Virginia, have repeatedly rejected the self-critical analysis privilege, particularly in connection with routine and voluntary safety audits.
- (C) Defendants Actavis cannot meet the four pronged self-critical analysis privilege test as delineated in *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970) and *Dowling v. American Hawaii Cruises, Inc.*, 971 F.2d 423, 426 (9th Cir. 1992).
- (D) The documents and testimony relating to the GMP compliance audit are highly relevant to Plaintiffs' claims in this litigation and Plaintiffs will be severely prejudiced if discovery of this information is denied.

For these reasons, Plaintiffs request the Court enter an order compelling Defendants Actavis to produce documents relating to the audit performed by Mr. Galea, as well as other GMP compliance audits performed prior to the Digitek recall. Plaintiffs also request the opportunity to re-depose Mr. Galea on this limited subject matter as well as other witnesses who have knowledge of this subject matter.

II. BACKGROUND

On June 9, 2009, the PSC served Plaintiffs' Second Set of Requests for Production on Defendants Actavis. The PSC specifically requested documents relating to internal audits conducted at the Actavis Totowa facilities. *See* Exhibit A, Excerpts from Defendants Actavis

Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC's Responses to Plaintiffs' Second Set of Request for Production, Request Nos. 74-77. In their responses which were served on July 20, 2009, Defendants Actavis asserted numerous objections and failed to produce any responsive documents. *See id.* Although Defendants Actavis asserted the attorney-client, attorney work product and joint defense privileges, there was no assertion of the self-critical analysis privilege. *See id.* Additionally, Defendants Actavis' Privilege Log contains no mention of the self-critical analysis privilege.

According to Mr. Galea, in December 2006 he was asked by Gundrun Eyolfssdottir, the head of quality for Actavis Group, to travel to the United States and perform an audit of Actavis Totowa LLC from a GMP perspective ("GMP compliance audit"). *See* Exhibit B, Excerpts from the Deposition of Paul Galea at 12:24-13:19; 25:11-26:18; 150:7-21. This was the first time that Plaintiffs were made aware of the existence of this GMP compliance audit. At the time of Ms. Eyolfssdottir's request, Mr. Galea was the Quality Assurance Manager of Actavis Limited in Malta, which is a subsidiary of Actavis Group in Iceland. *See id.* at 148:20-149:10. According to Mr. Galea, he was asked to perform the GMP compliance audit because he was a corporate auditor for Actavis Group. *See id.* 154:21-155:10. He testified that it is a routine part of the company's business to perform assessments of GMP compliance. *See id.* at 182:17-20. At no time during his deposition did Mr. Galea suggest that the GMP compliance audit was intended to remain confidential. Rather, he indicated that Ms. Eyolfssdottir simply asked if he would be willing to go to the United States to make the assessment. *See id.* at 26:11-27:1.

To accomplish this GMP compliance audit, Mr. Galea traveled to the United States on five occasions between February and August 2007. *See id.* at 23:2-24:18. Following completion

of the audit, Mr. Galea sent emails to Ms. Eyolfsdottir and Scott Talbott, who was the head of quality for Actavis Totowa LLC, and prepared a report with his recommendations which he believes he sent to the Quality Systems Department. *See id.* at 15:19-16:5; 27:10-29:22; 35:4-36:8. After completing this audit Mr. Galea was hired as an employee of Actavis Totowa LLC in October 2007. *See id.* at 43:8-20; 171:15-172:2.

Mr. Galea testified that GMPs are rules and guidelines relating to the manufacturing, packaging and testing of products, the objective of which is to assure a product's safety for human use. *See id.* at 158:16-160:18. He further testified that GMPs are applicable to all products manufactured by Actavis Totowa. *See id.* at 83:17-84:1. Despite his testimony that the purpose of the audit was to determine Actavis Totowa LLC's compliance with GMPs, which would necessarily include the manufacturing, packaging and testing of Digitek, Mr. Galea was repeatedly instructed by counsel for the Actavis Defendants not to answer questions about his assessment, his conclusions, or the objective facts underlying his assessment. *See id.* at 16-22; 35-40; 184-188; 194-195; 207; 217-218. As such, Plaintiffs were unable to extract any substantive information concerning the underlying facts of the audit or Mr. Galea's observations and conclusions.

III. ARGUMENT AND AUTHORITY

A. THE HISTORY OF THE "SELF-CRITICAL ANALYSIS" PRIVILEGE AND THE STRONG PRESUMPTION AGAINST THE PRIVILEGES.

Federal Rule of Evidence 501 generally leaves the area of privilege to the trial court's discretion. *See* FED. R. EVID. 501 ("Except as otherwise required by the Constitution . . . as provided by Act of Congress or in the rules prescribed by the Supreme Court . . . , the privilege

of a witness . . . shall be governed by the principles of common law as they may be interpreted by the courts of the United States in light of reason and experience”). In enacting Rule 501, Congress clearly rejected the creation of specific privileges in favor of providing the courts with greater flexibility. *See Trammel v. United States*, 445 U.S. 40, 47, 63 L. Ed. 2d 186, 100 S. Ct. 906 (1980) (stating that Rule 501 provides for development of privilege law on a “case-by-case basis”). There is a strong presumption against the application of privileges, and therefore privileges must be “strictly construed.” *See e.g., University of Pennsylvania v. EEOC*, 493 U.S. 182, 189 (1990); *Trammel*, 445 U.S. at 51. “The allowance of the privilege to withhold evidence that is demonstrably relevant in a . . . trial would cut deeply into the guarantee of due process of law and gravely impair the basic function of the courts.” *United States v. Nixon*, 418 U.S. 683, 712, 41 L. Ed. 2d 1039, 94 S. Ct. 3090 (1974).

The origination of the self-critical analysis privilege (sometimes referred to as the self-evaluative privilege) is widely considered to be from the case of *Bredice v. Doctors Hosp., Inc.*, 50 F.R.D. 249 (D.D.C. 1970), *aff’d mem.*, 479 F.2d 920 (D.C. Cir. 1973). In *Bredice*, a medical malpractice action, the plaintiff moved for discovery of medical review board meeting minutes and reports. 50 F.R.D. at 249. The court ruled that “confidentiality is essential to effective functioning of these staff meetings; and these meetings are essential to the continued improvement in the care and treatment of patients.” *Id.* at 250. Subjecting the discussions and deliberations to the discovery process, without a showing of exceptional need, would effectively terminate any further deliberations. *Id.* The *Bredice* court felt that constructive professional criticism would not occur out of fear that one doctor’s critique of another could be used in a malpractice suit against that colleague. *Id.*

Since *Bredice*, however, the privilege has remained “largely undefined and not generally recognized by many authorities.” *Etienne v. Mitre Corp.*, 146 F.R.D. 145, 147 (E.D. Va. 1993) (quoting *Guardian Life Insurance Co. v. Service Corp. Int'l*, 1989 WL 3496 *3 (E.D. Pa. Jan. 17, 1989)). To the extent it has been recognized, the self-critical analysis privilege shields from discovery certain institutional investigations, based upon the concern that the disclosure of documents reflecting candid self-examination will deter or suppress socially useful self-evaluation or compliance with the law or with professional standards. *See generally* Note, *The Privilege of Self-Critical Analysis*, 96 HARV. L. REV. 1083 (1983). Most often, the self-critical analysis privilege has been used in the context of post-accident reports. *See e.g.*, *Bredice*, 50 F.R.D. 249 (medical malpractice); *Hickman v. Whirlpool Corp.*, 186 F.R.D. 362 (N.D. Ohio 1999) (industrial accident). Internal evaluations done in the normal course of business have not been afforded the same protection. *See Dowling v. American Hawaii Cruises, Inc.*, 971 F.2d 423, 426 (9th Cir. 1992) (self-critical analysis privilege did not protect routine internal corporate reviews); *Reichhold Chemicals, Inc. v. Textron, Inc.* 157 F.R.D. 522, 527 (N.D. Fla. 1994) (privilege only applies to reports which were prepared after the fact for the purpose of self evaluation and analysis). The “fact that an actor had actual prior knowledge of the harm that would or could result from a course of action, and, nevertheless, deliberately chose to act is highly relevant . . . and should ordinarily be discoverable.” *Reichhold*, 157 F.R.D. at 527.

Even if the privilege is properly asserted, only self-evaluative or subjective impressions and opinions are protected -- not the objective facts or data considered in forming the impressions or opinions. *See e.g.*, *Dowling*, 971 F.2d at 425-426; *Freiermuth v. PPG Indus., Inc.*, 218 F.R.D. 694, 698 (N.D. Ala. 2003); *In re Air Crash Near Cali, Colombia on December 20,*

1995, 959 F. Supp. 1529, 1532 (S.D. Fla. 1997); *Webb v. Westinghouse Electric Corp.*, 81 F.R.D. 431, 434-35 (E.D. Pa. 1978).

B. BY FAILING TO ASSERT THE SELF-CRITICAL ANALYSIS PRIVILEGE IN RESPONSE TO PLAINTIFFS' DISCOVERY REQUESTS OR IN THEIR PRIVILEGE LOG, DEFENDANTS ACTAVIS HAVE WAIVED THE PRIVILEGE.

Federal Rule of Civil Procedure 34 requires a party to whom discovery is directed to assert proper objections to discovery requests. *See* FED. R. CIV. P. 34(b). Plaintiffs' Second Requests for Production Nos. 74-77 requested documents relating to internal audits and investigations conducted at Actavis Totowa facilities. *See* Exhibit A. Specifically, Request No. 75 sought "[a]ll documents or records relating to any internal audits conducted by the compliance division or any quality department in the last ten years at any of the facilities used by Actavis Totowa LLC, including but not limited to the Little Falls Facility, the Taft Road Facility and the Riverview Facility." *Id.* Defendants Actavis made numerous objections to this and related requests on the basis of relevance, scope and burden, and asserted the attorney work product, attorney-client and the joint defense privileges. *See id.* Defendants Actavis did *not*, however, assert the self-critical analysis privilege. *See id.* Moreover, Defendants Actavis have not asserted this privilege in their Privilege Log.

Though no federal court in this district has specifically addressed the issue of waiver of the self-critical analysis, many other courts have concluded that failure to timely assert this privilege results in waiver. *See Mills v. Energy Transp. Corp.*, 1997 U.S. Dist. LEXIS 20584 *8-9 (S.D.N.Y. Dec. 23, 1997) (finding that defendant's failure to assert privilege in response to plaintiff's document request waived the privilege); *Maxey v. GMC*, 1996 U.S. Dist. LEXIS 21136 *3-4 (N.D. Miss. Dec. 12, 1996) (finding that the failure to assert self-critical analysis

results in waiver of the privilege); *Zapata v. IBP, Inc.*, 1994 U.S. Dist. LEXIS 16285 *12-13 (D. Kan. Nov. 10, 1994) (holding that defendants waived the self-critical analysis privilege by failing to assert same in responses to request for production).

In *Ayers v. Continental Cas. Co.*, 240 F.R.D. 216 (N.D. W.Va. 2007), the court declined to decide whether the plaintiffs' failure to timely assert objections based on another privilege to defendant's interrogatories constituted an *automatic* waiver of the privilege. However, the court concluded instead that plaintiffs waived the privilege because (a) they failed to state any grounds for the privilege, (b) failed to assert a privilege for several months, and (c) could provide no good cause for the delay. In reaching this conclusion, the court considered the six part test delineated in *Hall v. Sullivan*, 231 F.R.D. 468, 474 (D. Md. 2005) for evaluating the propriety of waiver: (1) the length of the delay . . . (2) the reason for the delay . . . (3) whether there was any dilatory or bad faith action on the part of the party that failed to raise the objection properly; (4) whether the party seeking discovery has been prejudiced by the failure; (5) whether the . . . request was properly framed and not excessively burdensome; and (6) whether waiver would impose an excessively harsh result on the defaulting party. *Id.* at 223 (quoting *Hall*, 231 F.R.D. at 474).

In the present case, Plaintiffs served their Second Requests for Production on June 9, 2009. Defendants Actavis responded to these requests on July 20, 2009. No objection based on the self-critical analysis was asserted. Only five months later, following the depositions of several other Defendants Actavis' corporate witnesses, was this privilege raised for the first time. Defendants Actavis have neither supplemented their responses to Plaintiffs' Second Requests for Production with the documents sought by this motion nor updated their Privilege Log to include these documents.

Defendants Actavis profess that their search for documents utilizing the search terms agreed upon by the parties did not reveal documents relating to the 2007 GMP compliance audit. Whether or not this is accurate, it seems highly unlikely that Defendants Actavis failed to recognize the relevance, or overlooked, an audit performed over a seven month period in 2007 which specifically addressed whether the Actavis Totowa LLC's manufacturing, packaging and testing operations, including those relating to Digitek, were in compliance with federally mandated GMPs. As such, Defendants Actavis have waived the self-critical analysis privilege.

C. THE MAJORITY OF COURTS, INCLUDING THOSE IN THE FOURTH CIRCUIT, HAVE REFUSED TO RECOGNIZE THE SELF-CRITICAL ANALYSIS PRIVILEGE, PARTICULARLY IN CONNECTION WITH ROUTINE AND VOLUNTARY SAFETY AUDITS.

Plaintiffs could not locate a single case in which a Fourth Circuit court has adopted the self-critical analysis privilege. In fact, one Fourth Circuit court recently noted that the privilege is “of recent origin and one that is narrowly applied even in those jurisdictions where it is recognized.” *McDougal-Wilson v. Goodyear Tire & Rubber Co.*, 232 F.R.D. 246, 250 (E.D.N.C. 2005) (quoting *In re Air Crash at Charlotte, N.C. on July 2, 1994*, 982 F. Supp. 1052, 1054 (D.S.C. 1995) (citing *Warren v. Legg Mason Wood Walker, Inc.*, 896 F. Supp. 540, 542 (E.D.N.C. 1995) (noting that “two recent decisions by United States District Courts in the Fourth Circuit have concluded that the Fourth Circuit does not recognize the self-critical analysis privilege”).

The Fourth Circuit courts which have addressed the self-critical analysis privilege have overwhelmingly rejected its application. See *Witten v. A.H. Smith & Co.*, 100 F.R.D. 446, 449-54 (D. Md. 1984) (affirmative action plans and employment information reports), *aff'd per curiam*, 785 F.2d 306 (4th Cir. 1986); *Deel v. Bank of Am., N.A.*, 227 F.R.D. 456, 459 (W.D. Va.

2005) (bank audit relating to payroll practices); *McDougal-Wilson v. Goodyear Tire & Rubber Co.*, 232 F.R.D. 246, 249 (E.D.N.C. 2005) (affirmative action plans); *Tucker v. United States*, 143 F. Supp. 2d 619, 627-28 (S.D. W.Va. 2001) (medical peer review records); *Warren*, 896 F. Supp. at 543 (internal branch audits); *Etienne*, 146 F.R.D. at 149 (employer studies relating to equal employment opportunity law compliance); *In re Air Crash at Charlotte*, 982 F. Supp. 1052, 1055-56 (D.S.C. 1995) (airline audits relating to improved efficiency, safety and marketability); *but see, Brem v. DeCarlo, Lyon, Hearn & Pazourek, P.A.*, 162 F.R.D. 94 (D. Md. 1995) (recognizing privilege only on the context of medical peer review committee proceedings which were specifically protected from discovery in a civil action by Maryland statute).

Other federal courts have likewise rejected, or shown reluctance to recognize, the self-critical analysis privilege. *See Alaska Elec. Pension Fund v. Pharmacia Corp.*, 554 F.3d 342, 351 n. 12 (3d Cir. 2009) (self-critical analysis privilege not recognized in Pennsylvania or Third Circuit); *Burden-Meeks v. Welch*, 319 F.3d 897, 901 (7th Cir. 2003) (Seventh Circuit has not recognized the self-critical analysis privilege); *Union Pac. R.R. Co. v. Mower*, 219 F.3d 1069, 1076 n. 7 (9th Cir. 2000) (Ninth Circuit has not recognized the privilege.); *In re Kaiser Aluminum and Chemical Co.*, 214 F.3d 586, 593 (5th Cir. 2000) (Fifth Circuit has rejected the self-critical analysis privilege); *FTC v. TRW, Inc.*, 628 F.2d 207, 210 (D.C. Cir. 1980) (D.C. Circuit does not recognize the self-critical analysis); *Gordon v. Sunrise Senior Living Mgmt.*, 2009 U.S. Dist. LEXIS 89346 *3 (D. Colo. 2009) (self-critical analysis privilege is not recognized in the Tenth Circuit or Colorado); *Berner v. Carnival Corp.*, 2009 U.S. Dist LEXIS 35768 *3-4 (S.D. Fla. 2009) (Eleventh Circuit has not adopted the privilege); *MacNamara v. City of New York*, 2007 U.S. Dist. LEXIS 17478 *9, 12 (S.D.N.Y. 2007) (noting the uncertain

status of self-critical analysis privilege in Second Circuit); *Carr v. El Dorado Chem. Co.*, 1997 U.S. Dist. LEXIS 5752, at *3-5 (W.D. Ark. 1997) (Eight Circuit does not recognize the self-critical analysis privilege).

Several state courts have similarly rejected the self-critical analysis privilege. *See Cloud v. Superior Court*, 50 Cal. App. 4th 1552, 1559 (1996) (declining to recognize self-critical analysis privilege in California absent legislative codification in the evidence code); *Roman Catholic Diocese of Jackson v. Morrison*, 905 So.2d 1213, 1245 (Miss. 2005) (declining to recognize the privilege under Mississippi law); *Geggie v. Copper Tire & Rubber Co.*, 2005 WL 2179430, at *6 (Ohio Ct. App. 2005) (privilege is not recognized in Ohio); *Hawthorne Land Co v. Occidental Chem. Corp.*, 2003 U.S. Dist. LEXIS 11430 (E.D. La. 2003) (Louisiana has not embraced the self-critical analysis privilege); *Sabratek Liquidating LLC v. KPMG, LLP*, 2002 WL 31520993, at *3 (N.D. Ill. 2002) (no self-critical analysis privilege exists under Illinois law).

Furthermore, many courts have specifically rejected the use of the self-critical analysis privilege in the context of corporate audits and investigations. *See e.g., Deel*, 227 F.R.D. at 459, *supra* (bank audit relating to payroll practices); *Warren*, 896 F. Supp. at 543, *supra* (internal branch audits); *In re Air Crash at Charlotte*, 982 F. Supp. at 1055-56, *supra* (airline audits relating to efficiency, safety and marketability); *United States v. Allison Engine Co., Inc.*, 2000 U.S. Dist. LEXIS 12433 *3-5 (S.D. Ohio 2000) (quality control audits relating to products supplied to the U.S. Navy); *Paladino v. Woodloch Pines, Inc.*, 188 F.R.D. 224, 225-26 (M.D. Pa. 1999) (resort director of safety services investigation and prevention report); *In the Matter of: Mercury Finance Company of Illinois*, 1999 U.S. Dist. LEXIS 11236 *17 (N.D. Ill. 1999) (in securities fraud action, defendant accounting firm's peer review documents); *Pkfinans Int'l Corp*

v. IBJ Schroder Leasing Corp., 1996 U.S. Dist LEXIS 17375 *3 (S.D.N.Y. 1996) (bank audits); *Chemical Bank v. Affiliated FM Ins. Co.*, 1994 U.S. Dist LEXIS 2956 *1 (S.D.N.Y. 1994) (defendant insurer's internal investigation into plaintiff's insurance loss); *In re Salmon Inc. Sec. Litig.*, 1992 U.S. Dist. LEXIS 17280 *4 (S.D.N.Y. 1992) (in securities and treasury violations action, documents pertained to the nature, extent, and adequacy of the defendant's internal audit controls).

In *Dowling*, the Ninth Circuit refused to apply the privilege to protect voluntary routine pre-accident safety reviews undertaken by a cruise ship operator which may have disclosed that the defendant had knowledge of the dangers which resulted in an injury to the plaintiff in a Jones Act case. *See id.* The *Dowling* court noted that voluntary safety reviews are not protected by the self-critical analysis privilege as opposed to those that may have been prepared in response to a governmental mandate. *See id.* at 426-427. In the present case, the GMP compliance audit was not performed by Paul Galea in response to a governmental mandate. Rather, similar to the facts in *Dowling* and as confirmed by Mr. Galea, the GMP compliance audits were a routine part of the company's business. *See Exhibit B at 182:17-20.* Therefore, the GMP compliance audit should not be protected by the self-critical analysis privilege.

D. EVEN IF THE FOURTH CIRCUIT RECOGNIZED THE SELF-CRITICAL ANALYSIS PRIVILEGE, DEFENDANTS ACTAVIS CANNOT SATISFY THE FOUR PRONG TEST DELINEATED IN *BREDICE* AND *DOWLING*.

As discussed above, Plaintiffs do not believe the self-critical analysis is recognized in this Circuit. However, should the Court disagree, Defendants Actavis cannot show that the documents and testimony sought should be afforded the protection of this privilege. The test that has evolved from the *Bredice* decision requires that the party asserting the privilege demonstrate

that the material to be protected satisfies the following criteria: (1) the information must result from self-critical analysis undertaken by the party seeking protection; (2) the public must have a strong interest in preserving the free flow of the type of information sought; (3) the information must be of the type whose flow would be curtailed if discovery were allowed, and; (4) no document should be accorded the privilege unless it was prepared with the expectation that it would be kept confidential. *Bredice*, 50 F.R.D. 249; *Dowling*, 971 F.2d at 425-426.

The second and third prongs have often been analyzed by courts concurrently. *See e.g.*, *Etienne v. Mitre Corp.*, 146 F.R.D. 145, 147-148 (E.D. Va. 1993) (“Essentially, the court must determine whether the type of internal review conducted by the party invoking the privilege is one that benefits the public interest *and* would be curtailed in the future if it were subject to disclosure during civil discovery”). While acknowledging the public’s interest in the free flow of the information sought, many courts have also recognized that the flow of such information would not be curtailed if discovery were allowed. For example, the *Dowling* court observed that “such reviews will rarely, if ever, be curtailed simply because they may be subject to discovery ... Organizations have many incentives to conduct such reviews that outweigh the harm that might result from disclosure ... The most prominent of these is surely the desire to avoid law suits arising from unsafe conditions ... But organizations also have a strong incentive to avoid developing a reputation for having an unsafe premises.” *Dowling*, 971 F.2d at 426.

In *In re Air Crash at Charlotte*, 982 F.Supp. 1052, 1055 (D.S.C. 1995), where a defendant airline in an action concerning an airplane crash opposed disclosure of certain internal safety reports, the South Carolina district court observed:

It is beyond dispute that the airline industry is highly competitive and tightly regulated. Moreover, all airlines have a keen interest in advancing and promoting

safety as well as improving service. Airlines are, therefore, likely to conduct internal audits from time to time to insure improved efficiency (both in terms of service and economy), safety and marketability. While disclosure of these audits and other papers to competitors of U.S. Air would certainly deter use of them in the future, disclosure for limited use in litigation (such as to prove notice) is unlikely to deter their use.

982 F. Supp. at 1055; *see also*, *Allison Engine Co.*, 2000 U.S. Dist. LEXIS 12433, at *13 (S.D. Ohio 2000) (abandoning safety reviews would be bad for business); *In re Grand Jury Proceedings*, 861 F. Supp. at 390 (audits allow companies to avoid future civil liability); *Pkfinans Int'l Corp*, 1996 U.S. Dist. LEXIS 17375, at *3 (audits “will likely continue ... out of an obvious business necessity...”); *In re Salmon Inc., Sec. Litig.*, 1992 U.S. Dist. LEXIS 17280 *4 (internal audit reports are “so integral to the success of a business that the free flow of information is not likely to be stemmed by the possibility of future disclosure”).

With respect to a particular audit that was made in anticipation of a national aviation safety inspection by the Federal Aviation Administration, the *In re Air Crash at Charlotte* court further observed: “Given its purpose of helping the airline comply with FAA regulations, limited disclosure of the report, and documents relating to it, is unlikely to deter preparation of similar reports in the future.” 982 F. Supp. at 1055. In this case, Mr. Galea’s audit was performed to determine whether Actavis Totowa LLC was in compliance with federal GMPs. It is unlikely that Defendants Actavis will discontinue preparation of similar reports if Mr. Galea’s report and communications regarding the same are disclosed. Furthermore, manufacturers of pharmaceutical products, like the airlines and cruise ships, are highly competitive. They have a clear financial interest in complying with federal regulation when it comes to ensuring the safety of their manufacturing, packaging and testing operations which should prevent further admonishment by the FDA, additional product recalls, and future civil liability. To suggest the

future use of such audits would be curtailed if such information were disclosed in this litigation would be disingenuous.

With respect to the fourth and final prong, when questioned about the specifics of his assignment, Mr. Galea testified that he was simply asked if he would be willing to go to the U.S. to perform the GMP compliance audit. *See* Exhibit B at 26:11-27:1. Though his testimony was limited by counsel's repeated instructions not to answer, Mr. Galea never suggested that his assessment was confidential. As it clearly falls on Defendants Actavis to demonstrate that documents and testimony relating to Mr. Galea's 2007 GMP compliance audit, as well as any other GMP compliance audits, are protected by the self-critical analysis privilege, Plaintiffs will further address this prong, if necessary, after Defendants Actavis respond to this motion.

E. DOCUMENTS AND TESTIMONY RELATING TO THE GMP COMPLIANCE AUDIT ARE HIGHLY RELEVANT TO PLAINTIFFS' CLAIMS IN THIS LITIGATION AND PLAINTIFFS WILL BE SEVERELY PREJUDICED IF DISCOVERY OF THIS INFORMATION IS DENIED.

It is widely accepted that Federal Rule of Evidence 401's basic standard of relevance is a liberal one. *See e.g., Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 587, 113 S.Ct. 2786, 2794 (1993); *Nat'l Union Fire Ins. Co. of Pittsburgh, P.A. v. Murray Sheet Metal Co. Inc.*, 967 F.2d 980, 983 (4th Cir. 1992). The test for relevancy under the discovery rules is necessarily broader than the test for relevancy under Rule 402 of the Federal Rules of Evidence. *See* FED. R. CIV. P. 26(b)(1) ("relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence"). Any argument by Defendants Actavis that the requested documents are not relevant because the GMP compliance audit did not relate specifically to Digitek is without merit. Mr. Galea acknowledged that the manufacturing, packaging and testing operations he assessed as part of his GMP compliance

audit related to *all* products manufactured by Actavis Totowa LLC, including Digitek. What Defendants Actavis knew about the their ability to manufacture their products in compliance with GMPs in 2007, during which time Digitek was still being manufactured and distributed to the public, is particularly relevant to Plaintiffs' claims in this litigation. Even if the Court determines at a later date that the documents and testimony sought by Plaintiffs in connection with the GMP compliance audit are not admissible, Rule 401's liberal standard permits discovery into this subject matter.

Plaintiffs will be severely prejudiced if denied this information. The *Dowling* court emphasized the importance of disclosure of such information:

“[I]nformation regarding a company's response to the particular hazard, as well as its general safety procedures, will be invaluable to a plaintiff attempting to prove that his injury was caused by the company's negligent failure to make safe a hazardous condition. That information may reveal not only what the company knew of the condition, but whether it regarded it as dangerous, whether it assigned someone to repair the condition, what that person did, whether the company typically responded swiftly and effectively to hazardous conditions or allowed them to persist, and so on. Furthermore, the implications of such a rule would have major ramifications outside the area of negligence. A rule that manufacturers' reviews of the safety of their products are privileged from discovery would place a nearly insurmountable barrier in front of plaintiffs who must prove malice in order to obtain punitive damages in product liability actions. It would also create an enormous obstacle to claims that a manufacturer fraudulently concealed its knowledge of the health hazards of its products.

971 F.2d at 427 (internal citations omitted). The GMP compliance audit would undoubtedly shed light on Defendants Actavis' awareness and knowledge of potential dangerous conditions relating to their manufacturing, packaging and testing operations at their New Jersey facilities, well before many of the plaintiffs were injured and before Digitek was recalled. Therefore, Plaintiffs are entitled to this information.

IV. CONCLUSION

As Defendants Actavis failed to assert the self-critical analysis privilege in response to Plaintiffs' requests for production of documents relating to internal audits or in their Privilege Log, they have waived that privilege. However, even if the Court concludes that the privilege has not been waived, the overwhelming majority of federal and state courts, including those in West Virginia, have repeatedly rejected the self-critical analysis privilege particularly in connection with routine and voluntary safety audits such as the GMP compliance audit discussed herein. Furthermore, even if the Court concludes that the self-critical analysis can be asserted under these circumstances, Defendants Actavis cannot meet the four pronged self-critical analysis privilege test as they cannot demonstrate that the use of such audits will be curtailed in the future if the audits at issue in this case are made discoverable, or that the GMP compliance audits were meant to remain confidential. Lastly, the documents and testimony relating to the GMP compliance audit are highly relevant to Plaintiffs' claims in this litigation and Plaintiffs will be severely prejudiced if discovery of this information is denied.

Plaintiffs respectfully request that this Court grant this motion and enter an order compelling Defendants Actavis Totowa LLC, Actavis Inc., and Actavis Elizabeth LLC to produce documents and provide testimony relating to their Good Manufacturing Practices compliance audits.

Dated: December 29, 2009

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

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